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MANAGEMENT OF HARD TISSUE AVULSIVE WOUNDS
AND MANAGEMENT OF OROFACIAL FRACTURES

ANNUAL REPORT

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ABSTRACT

Ceramic and ceramic composite materials and devices were developed for specific maxillofacial applications. These applications included:

- (1) Replacement of hard tissue voids in low stress areas with a phosphate-bonded alumina-foamed ceramic and a calcium aluminate-bonded alumina foam.
- (2) Development of porous ceramic-coated metallic devices for stabilization of mandibles with avulsed segments.

Efforts to date have been rewarding. Using the rhesus monkey for all experimental implant work, incorporation of porous ceramic foam prostheses to eliminate maxillary defects has been accomplished. Also, we have succeeded in stabilizing the mandible where segments of from 3-8 mm were removed. Bridging of the gap with new bone occurred within six weeks resulting in a total regeneration of the resected area with restoration of normal mandibular function.

FOREWORD

This study has been conducted by the Ceramic Research Division of the Materials Engineering Department of Battelle Memorial Institute, Columbus, Ohio. This is the first annual report of progress under Contract No. DADA17-69-C-9118 "Management of Hard Tissue Avulsive Wounds and Management of Oro-facial Fractures". The principal investigator was Thomas D. Driskell, assisted by Martin J. O'Hara, principal ceramist. The valuable efforts of H. D. Sheets, Jr. and M. V. Weaver of the Ceramic Research Division, and Dr. Joseph R. Boatman and Dr. A. C. Peters of the Physiology and Pharmacology Division are gratefully acknowledged. Dr. George W. Greene, Jr., Chairman, Dr. Joseph Natiella and Dr. Jack Armitage, Assistant Professors, Department of Oral Pathology, School of Dentistry, State University of New York at Buffalo, served as consultant, histologist, and surgeon, respectively. In conducting the research described in this report, the investigators adhered to the "Guide for Laboratory Animal Facilities and Care" as promulgated by the Committee on the Guide for Laboratory Animal Resources, National Academy of Sciences - National Research Council.

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SUMMARY

Present day surgical techniques in many cases are unable to effect an adequate restoration for loss of hard tissue resulting from maxillofacial avulsive wounds. In these cases, the prognosis is generally poor from a functional, as well as from a cosmetic, point of view. What is needed for management of trauma of this nature is an effective means of hard tissue replacement or regeneration and improved methods of stabilization and permanent anchoring. Ceramic materials recently have been proposed and experimentally used as potential bone replacement materials.^{(1)*} Some ceramics possess properties which are highly desirable for a biomaterial. Among these are a high degree of inertness or lack of reactivity in the body environment and the propensity for both hard and soft tissue ingrowth in some porous ceramics. Unfortunately, ceramics are also extremely brittle and are, therefore, highly prone to fracture when subjected to tensile, torsional or sheer loads. Thus, the overall suitability of ceramics as biomaterials for many prosthetic applications becomes highly subject to the criteria demanded by the application. It is for this reason that we have limited this study to several maxillofacial restorative applications where we felt that the resultant material and devices developed could ultimately meet the criteria demanded by the normal function of that portion of the anatomy. The objectives of this program have been as follows:

- (1) To experimentally develop a low-density ceramic foam material for possible replacement of hard tissue in the maxillofacial area
- (2) To experimentally develop a high-strength porous ceramic material and experimentally fabricate potentially suitable implantable mandibular prostheses
- (3) To experiment with new or improved means of fixation for orofacial fractures. Concepts to be considered include ceramic-coated screws, plates, and other fixation devices
- (4) To investigate the potential applicability of Nitinol as a biomaterial with unique characteristics for both corrosion resistance and shrink-fit capabilities.

* References are listed on page 37.

These objectives are being fulfilled. However, Objectives 2 and 3 have become somewhat merged during the study so far. Our efforts to date have been rewarding. We have succeeded in stabilizing through and through resections of the mandible in rhesus monkeys without resorting to interdental wiring. Restoration of normal mandibular function has been accomplished experimentally. Incorporation of a porous ceramic prostheses to eliminate maxillary defects has also been demonstrated. These encouraging results, however, must be considered only as fortuitous preliminary efforts, pointing the way toward truly effective means of surgically correcting various maxillofacial defects.

PROBLEM AND APPROACH

Research on suitable implant materials and devices for replacement of hard and soft tissue has been conducted with varying degrees of success or failure, depending on one's attitude toward the subject at least since the beginnings of recorded history.⁽²⁾ Notwithstanding the magnitude of this effort, the choice of prosthetic implantable replacement parts remains highly selective with resultant appearance and function highly compromised in many instances. The reasons for lack of success with implants are many. The prime reason for failure involves tissue compatibility. No materials in widespread use today are completely compatible in all cases--they are merely tolerated to a greater or lesser extent.

Functional mismatch is another cause of failure. This can consist of inappropriate physical characteristics of the implant which are incompatible with the anatomy to which it is attached or the means by which the implant is attached. If the implant is a device that is pinned or screwed to a bone, the bone may resorb and the device will loosen. If the implant is merely to fill out a body contour, it may shift position or actually be extruded in a period of time due to inadequate attachment. Ideally, biomaterials should be nonreactive, selectively permit bone and tissue invasion or attachment when appropriate, and closely duplicate the mechanical properties of the anatomical material replaced.

Ceramic materials recently have been proposed and experimentally used as potential hard tissue replacement materials.⁽¹⁾ Some ceramics possess properties which are highly desirable for a biomaterial. Among these are a high degree of inertness or lack of reactivity in the body environment, and the propensity toward hard and soft tissue ingrowth in some porous ceramics. Certain parameters regarding the characterization of bioceramics have already been established and demonstrated. For example, it has been shown by Hulbert^(3,4) that bone will not invade a ceramic with a pore size under 40 microns. He further states that a pore size of approximately 200 microns with 100 micron interconnections appears to be ideal for proliferation of viable bone. The lack of reactivity⁽⁵⁾ of certain ceramic materials with tissue has been shown by Rhinelander⁽⁵⁾, Hulbert, and others. Unfortunately, ceramics are also extremely brittle and therefore highly prone to fracture when subjected to impact, tensile, or shear loads. Thus, the overall suit-

ability of ceramics as a biomaterial for many prosthetic applications becomes highly subject to the criteria demanded by the application. It is for this reason that we have limited our studies to several applications where we felt that the resultant materials and devices developed would ultimately meet the criteria demanded by the normal functions of that portion of the anatomy.

It was the intent of our studies to experimentally develop and evaluate ceramics and ceramic-coated devices with a potential for performing specific functions, and then design experimental prosthetic implant devices from these materials. Our efforts to date have been rewarding. A prototype device which could be adapted for either mandibular fracture fixation or for bridging a through and through avulsed section of a mandible received initial in-vivo evaluation. There has been no evidence to date of a materials compatibility problem. In addition, from the mechanical design standpoint it is evident that these devices are considerably more solid and provide greater stabilization than conventional devices. We have succeeded in stabilizing the mandible in monkeys where a sizable segment has been removed without resorting to interdental wiring. Ultimate bridging of the gap in a period of approximately six weeks resulting in a total repair of the resected area with restoration of normal mandibular function has been accomplished. Incorporation of porous ceramic prostheses to eliminate maxillary defects has also been accomplished.

Histologic studies to date concerned not only with the attachment of ceramic materials but also with biocompatibility indicate that there is apparently no adverse tissue response to the ceramic materials which we have been using. We would like to stress that we consider the work reported here as encouraging preliminary efforts pointing the way toward truly effective means of correcting various maxillofacial defects and improved prosthodontic techniques. It should also be remembered that the materials and devices developed so far have not been shown to be nontoxic or nonreactive in the human body. They have, however, functioned more than adequately in rhesus monkeys for periods up to six months.

MATERIALS AND METHODS

Our work in bioceramics may be conveniently broken down into two categories: (1) the development and application of ceramic foams, and (2) the development and application of ceramic-coated metallic devices. They will be discussed in that order.

Development of Low Density Ceramic Foam

Ceramic foam materials were developed for experimental use as nonstructural "building block" materials for hard tissue voids in the maxillofacial area. Two basic compositions were developed. A calcium

aluminate-bonded alumina foam was selected for development on the basis that similar materials have been demonstrated, by Hulbert et al.^(3,4), to be bio-compatible and to permit bone and tissue invasion. A phosphate-bonded alumina foam was selected for development on the basis of work conducted at Battelle that indicated that these materials could be easily fabricated, develop high strengths at a low (650 F) curing temperature, and show good resistance to fracture under impact loading. Experimental compositions, details of materials preparation, and properties of cured and/or fired ceramic foam materials are compiled in Tables 1 and 2.

Ceramic foam mixes were prepared by a whipping technique using a common household type Sunbeam mixer. Bar samples, 1-inch square by 7-inch long were cast from the calcium aluminate-bonded alumina foams, air set overnight (16 hours), cured at 220 F, and subsequently fired to either 2500 or 2700 F to develop a strong sintered bond. Initially, phosphate-bonded alumina foam samples were cast into porous alumina molds, 1-1/4 inches in diameter by 1 inch thick, to facilitate moisture removal without bond migration or sample bloating. Subsequently, gobs of the prepared phosphate-bonded alumina foam mix were successfully cured on 4-inch-diameter watch glasses. All phosphate-bonded alumina foams were first heated at 140 F overnight and finally cured at 100 F increments per hour to 650 F for 4 hours to develop a strong, chemically bonded structure. The feasibility of rapidly processing phosphate-bonded alumina foams by microwave heating was also investigated.

Each of the ceramic foams was characterized for porosity, density, compressive strength, and pore size distribution. Calcium aluminate-bonded alumina foams were prepared at four porosity levels: 46.6, 51.1, 56.0, and 62.4 percent. The phosphate-bonded alumina foam had a porosity of 48.2 percent. Both the calcium aluminate-bonded foam (Composition 29-6), and the phosphate-bonded foam had pore sizes ranging from about 0.05 to 0.4 mm, with most of the pores interconnecting. Calcium aluminate-bonded foams fired at 2500 F were slightly weaker than foams fired to 2700 F. More sintering occurs at the higher temperature to develop stronger structures. Also, the high-temperature-fired calcium aluminate-bonded foams showed slightly higher porosity values than foams of the same composition fired at 2500 F. Studies at Battelle have shown that cast, calcium aluminate-bonded bodies undergo an expansion when heated from 2500 to about 2730 F. The higher porosity of samples fired at 2700 F is associated with that expansion. Phosphate-bonded alumina foams (Composition 29-10) cured at 650 F were very strong, having an average compressive strength of over 8,000 psi, which is higher than the values for the calcium aluminate-bonded foam (Composition 29-4) fired at either 2500 or 2700 F.

A photograph of samples, property data, and microstructures of ceramic foam materials used as nonstructural hard tissue void fillers is shown in Figure 1. Small specimens, 1/4 inch square by about 1/2 inch long, were cut from foamed ceramic samples using a diamond saw. Subsequently, the specimens were further sized and shaped in preparation for implanting in rhesus monkeys using a small, high speed drill with a diamond mounted point.

TABLE 1. COMPOSITIONS, PREPARATIONS, AND PROPERTIES OF FIRED
CALCIUM ALUMINATE-BONDED FOAMED ALUMINA FOR
IMPLANT STUDIES

Materials	Compositions ^(a)			
	29-1	29-3	29-4	29-6
Alumina ^(b) , XA-15, grams	90.00	20.00	20.00	15.60
Alumina ^(b) , T-61, -325 mesh, grams		70.00	70.00	54.40
Calcium Aluminate Cement ^(b) , grams	10.00	10.00	10.00	30.00
Egg Albumin ^(c) , grams	0.50	0.50	1.00	1.00
Product BCO ^(d) , grams			0.03	0.03
Distilled Water, ml.	26.00	22.00	22.00	22.00
<u>Batch Preparations</u>				
Mixing, Speed Setting ^(e)	No. 1	No. 1	No. 3	No. 3
Mixing Time, minutes	10	10	14	14
Whipping Speed Setting	No. 3	No. 3	No. 6	No. 6
Whipping Time, minutes	3	3	2	2
Air Set Time, hours	18	18	18	18
Curing Time at 220 F, hours			2	2
<u>Properties^(f)</u>				
Percent Porosity				
Fired to 2500 F			46.6	56.0
Fired to 2700 F			51.1	62.4
Apparent Density, g/c.c.				
Fired to 2500 F			2.03	1.60
Fired to 2700 F			1.93	1.44
Compressive Strength, psi				
Fired to 2500 F			6,200	3,480
Fired to 2700 F			7,080	3,690
Pore Size Range, mm			0.03-0.3	0.05-0.4

(a) Compositions designated according to last 2 numbers of Laboratory Record Book No. 26929 and page number.

(b) Alcoa, East St. Louis, Illinois.

(c) Nutritional Biochemicals Corporation, Cleveland, Ohio.

(d) Surface Active Agent, du Pont, Wilmington, Delaware.

(e) Sunbeam Mixer, Model MMA.

(f) Porosity, density and strength data represent average values measured on five, 1/2-inch cube specimens.

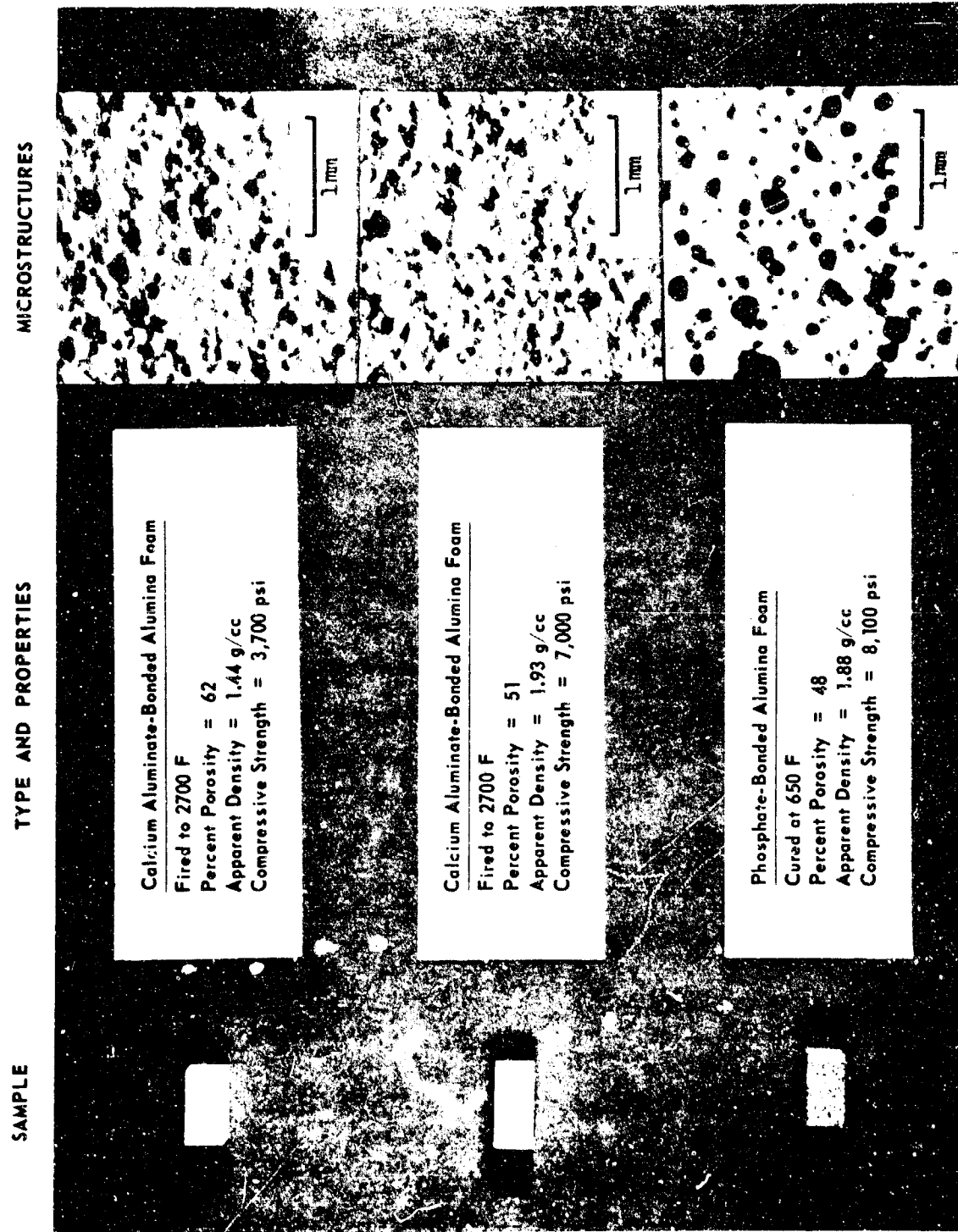
TABLE 2. COMPOSITIONS, PREPARATIONS, AND PROPERTIES OF
PHOSPHATE-BONDED FOAMED ALUMINA FOR IMPLANT
STUDIES

Materials	Compositions (a)			
	29-5	29-7	29-9	29-10
Alumina(b), XA-15, grams	21.00	----	----	20.00
Alumina(b), T-61, -325 mesh, grams	74.00	17.00	17.10	80.00
Aluminum Hydroxide(b), grams	5.00	1.70	0.70	----
Alumina Bubbles(c), grams	----	81.30	82.20	----
Egg Albumin(d), grams	1.00	----	----	----
Phosphoric Acid(e), (85%), ml	11.00	8.80	5.00	10.00
Product BCO(f), grams	----	----	----	0.06
Distilled Water, ml	11.00	8.80	5.00	10.00
Batch Preparations				
Mixing Speed Setting(g)	No. 3	No. 1	No. 1	No. 3
Mixing Time, minutes	12	4	4	12
Whipping Speed Setting	No. 6	----	----	No. 6
Whipping Time, minutes	2	----	----	2
Curing Method(h)	M	M	M	M, Q
Curing Temperature, F	(1)	(1)	650	650(j)
Properties (k)				
Percent Porosity				
Fired to 2500 F	----	----	58.10	----
Cured to 650 F	----	----	----	48.20
Apparent Density, g/cc				
Fired to 2500 F	----	----	1.46	1.88
Cured to 650 F	----	----	----	----
Compressive Strength, psi				
Fired to 2500 F	----	----	770	----
Cured to 650 F	----	----	----	8140
Pore Size Range, mm	----	----	----	0.05-0.4

NOTE: Footnotes appear on the following page.

FOOTNOTES FOR TABLE 2

- (a) Compositions designated according to last 2 numbers of laboratory Record Book No. 26929 and page number.
- (b) Alcoa, East St. Louis, Illinois.
- (c) Duralum P-163, 36 F, Washington Mills Abrasive, North Grafton, Massachusetts.
- (d) Nutritional Biochemicals Corporation, Cleveland, Ohio.
- (e) Reagent grade, Allied Chemical, Morristown, New Jersey.
- (f) Surface Active Agent, du Pont, Wilmington, Delaware.
- (g) Sunbeam Mixer, Model MMA.
- (h) "M" indicates microwave heated; "O" indicates oven heated.
- (i) Cast specimens bloated extensively during curing.
- (j) Microwave cured specimens bloated. Oven cured specimens were heated at 140 F overnight and subsequently heated at 100 F per hour to 650 F and soaked at temperature for 4 hours.
- (k) Porosity, density and strength data represent average values measured on five, 1/2-inch-cube specimens.



CERAMIC FOAM MATERIALS FOR USE AS NONSTRUCTURAL HARD TISSUE VOID FILLERS

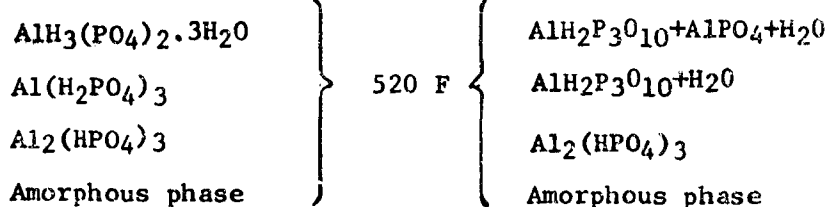
FIGURE 1.

Phosphate-bond alumina foams were more difficult to shape than any of the calcium aluminate-bonded samples. This may be attributed partially to differences in microstructures. The phosphate-bonded foams contained, on the average, larger pores than the calcium aluminate-bonded foams. The pore structure of the phosphate-bonded foams appeared to be more suitable for permitting bone proliferation and ingrowth.

Phosphate-bonded bodies must be cured to about 650 F to develop a stable, nonhygroscopic bond that is relatively resistant to dissolution in room temperature water⁽⁶⁾. The strength of phosphate-bonded bodies increases with curing temperature up to about 1000 F and then shows a gradual decrease to about 2500 F. Studies on the bonding products of aluminophosphates have been reported⁽⁷⁻¹³⁾. The systems most extensively studied consist of mixtures of aluminum hydroxide and phosphoric acid. However, the studies indicated that the reaction products of alumina and phosphoric acid are similar to those for aluminum hydrate-phosphoric acid mixtures. Therefore, physiochemical studies on aluminophosphate binders of the latter system provide some insight into the bonding products of alumina-phosphoric acid mixtures.

Aluminophosphate binders contain several phases which vary in distribution depending on the starting ratio of aluminum hydrate and acid. Thus, a given system may contain one or more of the following phases produced in a aluminum hydrate-acid mixture with an Al_2O_3 to P_2O_5 ratio of 2.3:

Initial Binder



Phosphoric acid reacts with alumina at about 250 to 300 F to form the same initial bonding hydrated phases. Monoaluminum phosphate, $\text{Al}(\text{H}_2\text{PO}_4)_3$, is a water soluble, hygroscopic phase. Upon heating the binder mixture above about 520 F, some new phases develop. Monoaluminum phosphate is converted to $\text{AlH}_2\text{P}_3\text{O}_{10}$, a more stable, water insoluble phase. In practice, a curing temperature of about 650 F is generally required to assure complete conversion of monoaluminum phosphate or other possible phases which are water soluble or hygroscopic.

Although the thermochemical properties of aluminophosphate binders have been studied more extensively in recent years, essentially no information is available on the physical properties of phosphate-bonded bodies cured at low temperature. Since the bonding materials consist of some hydrous aluminum phosphates, physical properties such as modulus of elasticity and impact strength may differ appreciably from that of the more brittle, sintered ceramics. Proprietary work at Battelle has shown that phosphate-

bonded bodies have higher resistance to fracture under impact loading than comparable resin-bonded bodies with a lower modulus of elasticity and nearly twice the bend strength. Studies to characterize phosphate-bonded bodies cured at low temperatures for such properties would be beneficial toward assessing the potential use of such ceramics for bone prostheses.

Initial studies showed that acceptable calcium aluminate-bonded foams were not attained with Compositions 29-1 and 29-3 containing only egg albumin as the foaming agent. Examination of fractured surfaces of cast and dried samples showed little porosity and the pore size range was not adequate. Product BCO, a silicone base wetting agent, was used as the foaming agent in Composition 29-10, a phosphate-bonded alumina foam. In Compositions 29-4, 29-6, and 29-10, a mixture of alumina powders was used to develop a strong structure. XA-15 alumina, a fine grain powder (mean particle size of 2.5 microns), is a reactive or sinterable material. This material provides more surface area and particle contact points where chemical bonding can take place in order to enhance the strength of phosphate-bonded foamed alumina structures.

Attempts to rapidly cure phosphate-bonded alumina foams of Compositions 29-5 and 29-10 by microwave heating have been disappointing so far. All samples showed extensive bloating. Cast foam samples were contained in 1-inch square by 6-inch long polyethylene molds and cured in a Varian industrial microwave unit powered with a Model PPS-2.5A Power Pack at a frequency of 2450 MHz. Slow microwave heating at minimum power inputs of 200 watts did not overcome the problem of bloating.

Lightweight, open structure phosphate-bonded samples of Compositions 29-7 and 29-8 containing alumina bubbles were successfully microwave cured. However, the samples were weak. Also, use of the alumina bubbles precludes attaining any appreciable amount of acceptably large, open and interconnecting porosity. Further research is needed to develop chemical-bonded foam materials which can be rapidly cured by microwave heating.

Figure 2 shows bone growing into phosphate-bonded alumina foam ceramic 45 days after implantation. This photomicrograph and Figure 3 were prepared as part of an implant study⁽¹⁴⁾ of our materials conducted at the U. S. Army Institute of Dental Research under the direction of Col. S. N. Bhaskar. Both phosphate-bonded alumina and calcium aluminate-bonded alumina foams were implanted in the tibia of rats for varying lengths of time in this study. Figures 4 and 5 are roentgenograms of a piece of phosphate-bonded alumina foam implanted in the maxilla of a rhesus monkey for a period of 4 months. Close examination of the tissue adjacent to the implant indicated no evidence of inflammatory cells. Examination of decalcified sections through the implant site revealed that the pores in the ceramic were completely filled by new bone similar in appearance to the bone growing into phosphate-bonded alumina foam implanted in rat femurs. It would be nice to end the discussion on low density ceramic foam implants at this point. Unfortunately, in many of our implant cases in rhesus monkeys the ceramic did not remain in place. The mechanism by which the material was lost is not known. It may have been simply picked out by the monkey. In retrospect, it is evident that

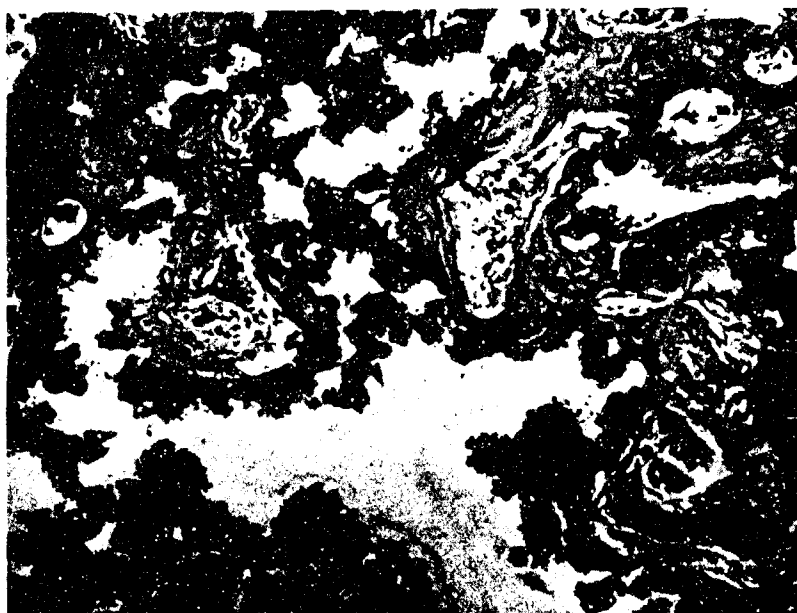


FIGURE 2. PHOTOMICROGRAPH SHOWING BONE INGROWTH
INTO PHOSPHATE-BONDED CERAMIC FOAM
IMPLANTED IN RAT TIBIA FOR 42 DAYS

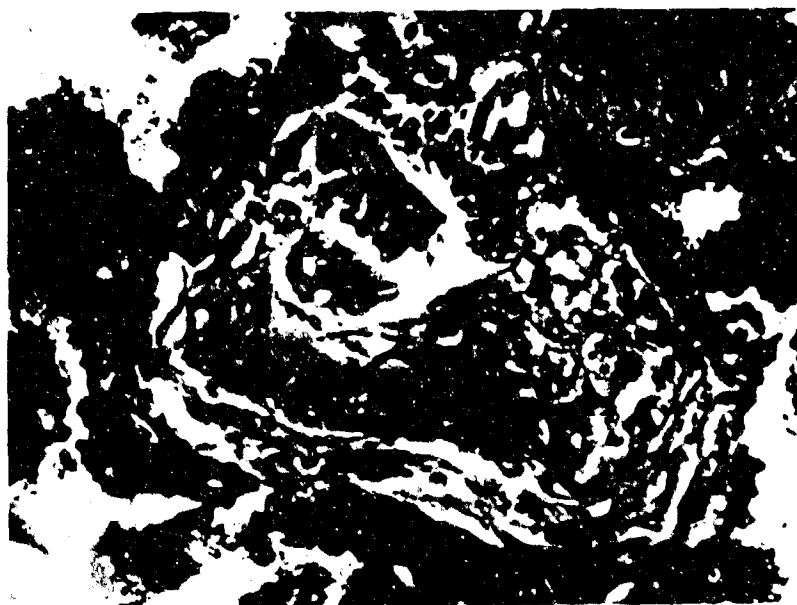
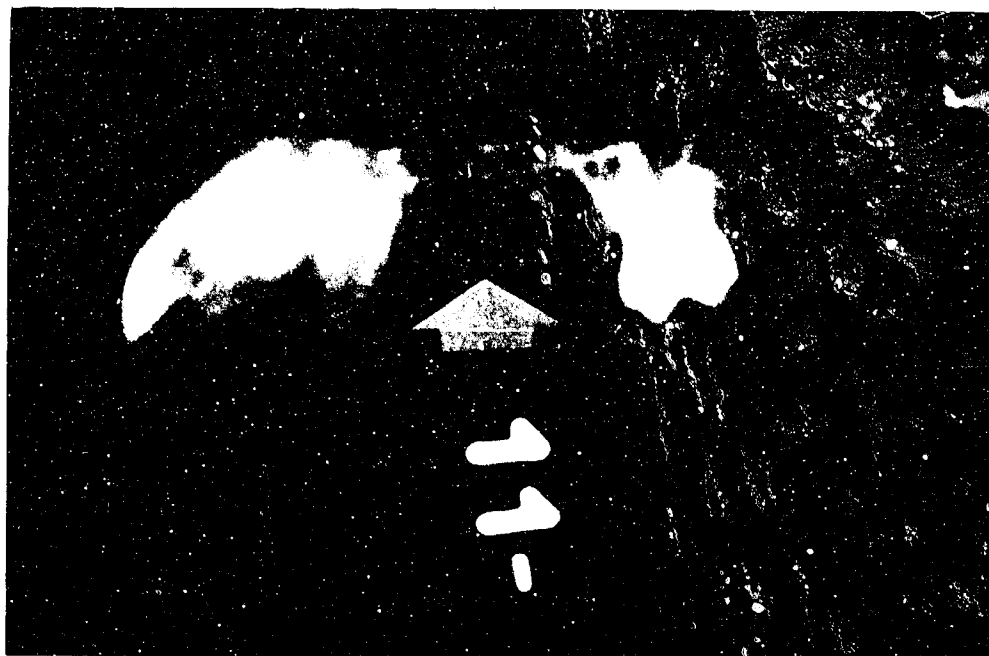


FIGURE 3. ENLARGEMENT OF LOWER RIGHT-HAND CORNER
OF FIGURE 2



FIGURES 4 AND 5. ROENTGENOGRAPHS OF CROSS SPECIMEN OF RHESUS MONKEY MAXILLA SHOWING PHOSPHATE-BONDED ALUMINA CERAMIC FOAM SPECIMEN 4 MONTHS AFTER IMPLANTATION

oral examination of the implant sites was not frequent enough to observe this disappearance phenomenon. Infection was the probable cause of rejection in at least one case. The implant sites in the other instances did not manifest any remarkable characteristics. It is interesting to note, however, that marginal resections of the rhesus monkey mandible with removal of both buccal and lingual plates did not result in significant bone defects even after the ceramic foam implant was rejected from the site.

Marginal Resection Procedure for Placement of Ceramic Blocks into Mandibular and Maxillary Defects

Rhesus monkeys were the experimental animal. Implants were placed in both the maxilla and the mandible. A mucoperiosteal flap was turned and the marginal resection of the mandible or maxilla was accomplished by the use of a fissure burr in a straight handpiece utilizing sterile saline spray. Bone was removed from one-half to two-thirds of the superior-inferior dimension of the mandible or maxilla. The blocks were trimmed to effect a tight fit into the defect and closed with catgut sutures. In the cases where exfoliation has occurred, only in one instance was there an obvious area of site infection which could be visualized grossly. In those cases where the implant remained in place for periods of three months, histologic examination disclosed that the porosity of the ceramic material was completely filled with osteoid and bone. There was no evidence of adverse tissue response in these cases. Those sites where exfoliation of the ceramic implants occurred had the following features. In all cases epithelium had covered the defect site; in most cases the underlying connective tissue did not contain an inflammatory infiltrate. The site contained trabecular bone that was normal in all respects usually having the characteristics of functional bone. No evidence of foreign body reaction was seen. Figures 4 and 5 are roentgenographs showing a phosphate-bonded alumina foam pellet in the maxilla of a rhesus monkey.

Development of Ceramic-Coated Devices

Considerable effort was devoted to the development and evaluation of ceramic-coated metallic fixation devices. Commonly, stabilizing devices of surgical grade metals are used either on a temporary or permanent basis to permit healing of injured bone and/or to function as the natural body structure. However, implanted metals, to varying degrees, are subject to corrosion and degradation by body fluids producing, in some instances, toxic products and undesirable effects⁽²⁾. This severely limits the use of such materials for permanent prostheses. Metallic devices with impervious glass enamel coatings and overlying oxide ceramic coatings, designed to permit tissue attachment and/or bone ingrowth, were developed and evaluated in this study. Metallic substrate materials selected for this study were 316 surgical grade stainless steel, tantalum, and vitallium. Methods investigated to achieve ceramic oxide coatings on devices were flame and plasma spraying and application of phosphate-bonded alumina coatings.

Glass Coatings

In the development of ceramic-coated devices, preliminary efforts were devoted to the preparation and application of glass coatings. Coating compositions are given in Table 3. Clay and bentonite were used as suspending agents. Mill additions of potassium nitrate and magnesium carbonate were used, respectively, to improve the tearing resistance and to maintain the refractoriness of the coating. Two commercially available frits were used. Frit 5210, a highly acid and alkaline resistant frit, fused at 1600 F. Frit XT-79 fuses at 1470 F and is considered to have good acid and alkaline resistance. In preparing enameling slips, the frit and mill additions were wet ball milled for 18 hours so as to attain a fineness of about 0.1 to 0.2 gram of material per 100 gram of slip retained on a 325 mesh screen.

Experimental coating application and firing trials were made to establish coating thicknesses and time-temperature schedules for obtaining optimum coatings. Coatings were applied to experimental samples of the three selected substrate materials by spraying at a line air pressure of 45 psi. Information on specimen description and preparation, processing details, and evaluation of samples is compiled in Table 4.

Acceptable, thin impervious glass coatings were attained on all of the substrate materials with the Composition C-17 enamel. Essentially standard procedures were followed in processing the samples⁽¹⁵⁾. About 0.23 gram of sprayed and dried enamel coating per 3 square inches of substrate surface was required to obtain fired coatings approximately 1-mil thick. The surface of all samples was first roughened by either vapor or sand blasting to promote good mechanical bonding of glass enamel coatings⁽¹⁵⁻¹⁷⁾. Spray-coated stainless steel and Vitallium specimens were fired in an air atmosphere to oxidize the substrate surface and enhance chemical bonding⁽¹⁶⁾. Tantalum specimens required sand blasting and oxidation of the surfaces to obtain adherent coatings. All coated tantalum specimens were fired in an argon atmosphere to prevent excessive oxidation. Enamel Composition C18 coatings on tantalum were poor. The coatings contained pinholes and black specks, which may have resulted from oxidation of tantalum and reduction of titania particles contained in the frit. Micrographs showing cross sections of glass enamel coatings on metal substrates are shown in Figure 6.

Ceramic Coatings

Various methods to apply ceramic coatings on glass-coated or uncoated stainless steel, Vitallium, or tantalum coupon specimens were investigated. Details of application and evaluation of ceramic coatings are compiled in Table 5. Phosphate-bonded alumina coatings of Composition 29-10 were applied to glass-coated tantalum coupon specimens by troweling. The specimens then were heated at 100 F per hour to 550 F for 4 hours and subsequently ground to the desired thickness of about 20 mils. Alumina coatings were plasma sprayed directly onto coupon specimens. Typical glass-coated specimens with applied ceramic oxide or phosphate-bonded alumina coatings are shown in Figure 7. The porous phosphate-bonded alumina coatings on Specimen 40 was very adherent and could not be separated from the

TABLE 3. PORCELAIN ENAMEL COATING COMPOSITION

Materials	Compositions (a)	
	29-C17	29-C18
Frit 5210(b), grams	1,000.00	
Frit Xt-79(b), grams		1,000.00
Black Lable Clay(c), grams	50.00	50.00
Potassium Nitrate(d), grams	0.63	0.63
Bentonite(e), grams	2.50	2.50
Magnesium Carbonate(f), grams	2.50	2.50
Distilled Water, ml	550.00	550.00

(a) Designation of Compositions is the same as described in Table 1.

(b, c) Ferro Corporation, Cleveland, Ohio.

(d) Reagent grade.

(e) Type No. 1, National Lead Company, New York, N. Y.

(f) Reagent grade.

TABLE 4. PRELIMINARY PREPARATION AND EVALUATION OF GLASS ENAMEL-COATED
316 STAINLESS STEEL, TANTALUM, AND VITALLIUM SPECIMENS

Specimen	Specimen Size, inches	Specimen Preparation	Glass Enamel Coating (a)	Enameling Treatment			Coating Evaluation
				Atmosphere	Temperature, F	Time, min	
<u>316 Stainless Steel Specimens</u>							
22A	1x3x0.050	(b)	Cl8	Air	1600	5	Underfired
22B	Ditto	(b)	Cl8	Air	1600	8	Good
22C, D & E	"	(b)	Cl8	Air	1600	7	Good
22F, G & H	"	(b)	Cl7	Air	1800	6	Good
<u>Tantalum Specimens</u>							
24A	1/2x2-1/2x0.030	(c)	Cl8	Argon	1520	10	Poor
24B (e)	1/2x2-1/2x0.030	(c)	Cl7	Argon	1750	10	Underfired
37A	1/2x1x0.030	(d)	Cl7	Argon	1800	10	Overfired
37B	Ditto	(d)	Cl7	Argon	1800	8	Good
39A	"	(d)	Cl7	Argon	1800	6	Underfired
39B	"	(d)	Cl7	Argon	1760	10	Good
<u>Vitallium Specimens</u>							
36A & B	1/2x1x0.054	(a)	Cl7	Air	1800	8	Good

NOTE: Footnotes appear on following page.

All specimens were fired in a resistance heated tube furnace.

FOOTNOTES FOR TABLE 4

- (a) All specimens were spray-coated with the enamel slurry using a Devilbliss Type CM 501 spray gun at a line air pressure of 45 psi. The specimens were coated so as to contain about 0.23 gram of dry coating coating per 3 square inches of metal surface.
- (b) Vapor blasted, cleansed by boiling in a solution of 3 parts Alccnox detergent (Alconox, Inc., New York), 100 parts water.
- (c) Vapor blasted and oxidized at 1200 F in an air atmosphere for 3 minutes.
- (d) Sand blasted and oxidized as above.
- (e) Coating had poor adherence as apparent from large fragments breaking off when the specimen was crimped.



FIGURE 6. MICROGRAPHS SHOWING CROSS SECTIONS OF GLASS-ENAMEL COATINGS (COMPOSITION C17) ON 316 STAINLESS STEEL AND TANTALUM

TABLE 5. APPLICATION AND EVALUATION OF CERAMIC COATINGS ON GLASS ENAMEL-COATED AND UNCOATED 316 STAINLESS STEEL, TANTALUM, AND VITALLIUM

Specimen	Metal or Alloy	Glass Enamel (a) Coating	Sample Preparation	Type Ceramic Overcoat	Method of Application	Coating Thickness, mils	Evaluation
62A, B&C	Tantalum	C17	None	(b) Al_2O_3	Plasma sprayed (e)	5-10	Very adherent overcoat
38B	Tantalum	None	Vapor blasted	Al_2O_3 (b)	Ditto	10-15	Adherent to most of surface
38A	Vitallium	C17	None	Al_2O_3 (b)	"	10-15	Poor adherence
38C	Vitallium	None	Vapor blasted	Al_2O_3 (b)	"	10-15	Ditto
60	Vitallium	None	Sand blasted	Al_2O_3 (b)	"	5-10	"
30C	Stainless Steel	C17	None	Al_2O_3 (c)	Flame sprayed	5	Coating spalled off
30E	Stainless Steel	C17	None	Al_2O_3 (d)	Flame sprayed	5	Coating spalled off
40	Tantalum	C17	None	Composition 29-10	Troweled on and heated to 650 F	10	Very adherent overcoat
34	Stainless Steel	C17	None	Composition 29-10	Ditto	10	Coating spalled off
36	Vitallium	C17	None	Composition 29-10	"	10	Coating spalled off
32A	Stainless Steel	C18	None	Composition 29-6	Bonded to glass coating by heating	5	Localized spalling of overcoat and glass
32B	Stainless Steel	C17	None	Composition 29-6	Ditto	5	Ditto
33A	Stainless Steel	C17	None	Composition 29-6	Phosphate bonded to glass	10	No adherence

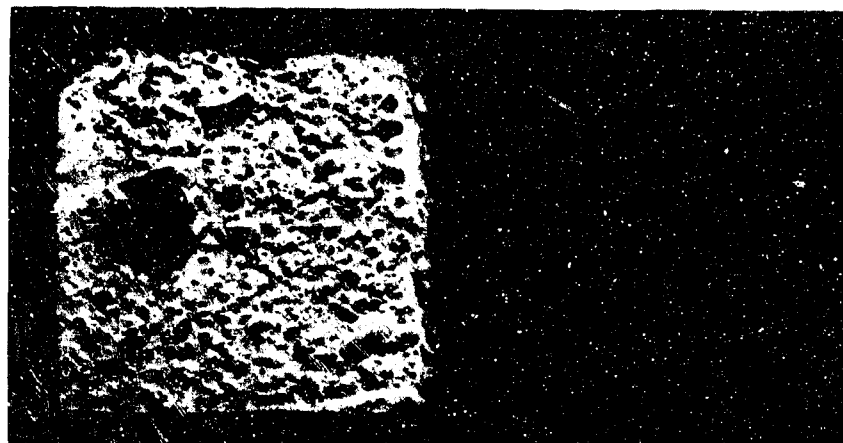
(a) Glass enamel coatings were applied and fired according to predetermined procedures noted in Table 4 to attain optimum coatings.

(b) Plasmalloy 331-F plasma-spray grade Al_2O_3 , 99.5%, -270 mesh, Plasma-Lyne, Santa Ana, California.

(c) Jet Spray Powder, Metallizing Company of America, Chicago, Illinois.

(d) T-61 alumina, minus 65 plus 100 mesh, Alcoa, East St. Louis, Illinois.

(e) Coatings sprayed with an Avco plasma gun, Model PG-100. Operating parameters were 600 amps, 28 V.D.C., 0.65 cfm arc gas (argon), 0.15 cfm powder carrier gas (argon).



4X

2E170

Porous Phosphate-Bonded Coating on
Glass-Enamel-Coated Tantalum Coupon, No. 40



4X

2E167

Plasma Sprayed Alumina Coating on
Glass-Enamel-Coated Vitallium Coupon, No. 38A

FIGURE 7. CERAMIC COATINGS ON GLASS-ENAMEL-COATED
TANTALUM AND VITALLIUM

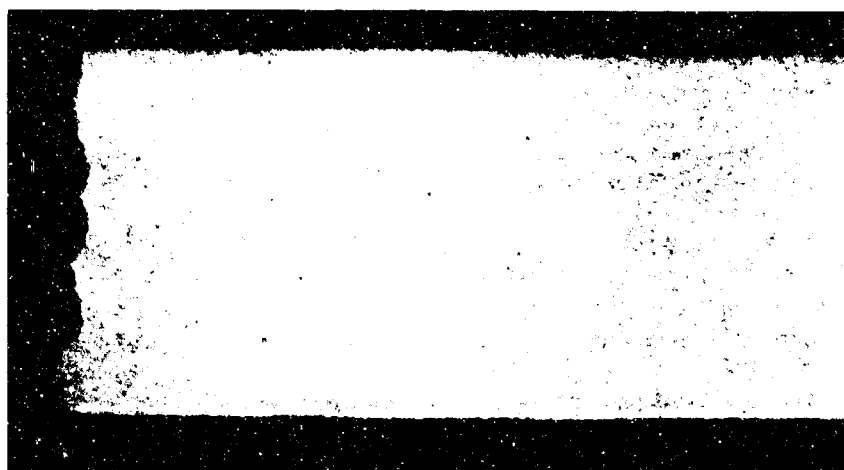
specimen without removing the underlaying glass. Coating of Composition 29-10 applied to glass-coated stainless steel and Vitallium specimens spalled or were nonadherent after the samples cooled. The plasma-sprayed alumina coatings on glass-coated Vitallium was not adherent over all of the surface, and sections of the coating were easily pried free.

Application of plasma-sprayed alumina coatings on uncoated and vapor blasted tantalum and Vitallium coupons also was investigated. Coated specimens are shown in Figure 8. An adherent plasma-sprayed alumina coating was applied to the tantalum specimen. However, complete coverage on edge surfaces of the specimen could not be attained. The plasma-sprayed alumina coating on Vitallium was nonadherent.

Other methods investigated to apply porous coatings on glass-coated stainless steel specimens were flame spraying alumina, and sintering and chemical bonding of prepared foam materials. Thin flame-sprayed alumina coatings spalled as the samples cooled. Careful application of the coating without appreciable heating of the substrate did not overcome the problem. Sliced thin sections (about 20 mils thick) of prepared calcium aluminate-bonded foam (Composition 29-6), were placed against glass-coated surfaces of stainless steel coupons, Nos. 32A and B. These coupons were packed in alumina sand, and heated to 1350 and 1600 F, respectively, to develop glass bonding of the coating to the substrate. Coatings applied in that manner spalled when cooled and removed portions of the underlying glass coating. Coatings applied in a similar manner using mixed Composition 29-10 materials as a cementing media and curing to 650 F were nonadherent.

Specimens were evaluated for adherence of glass coatings and phosphate-bonded and plasma-sprayed alumina coatings on glass-coated tantalum. The adherence of coatings was evaluated by measuring the force required to pull free a 1/2-inch-diameter section of the coating from each specimen. Measured average values of adherence for phosphate-bonded alumina and plasma-sprayed alumina coatings on glass enameled tantalum substrate were, respectively, 180, 180, and 320 psi. In evaluating phosphate-bonded and plasma-sprayed alumina coatings, much of the underlying glass coating was removed, indicating that the ceramic oxide coatings were strongly bonded to the glass coating.

Tantalum was selected for making fixation devices since the most satisfactory combined glass enamel and ceramic oxide coatings were applied to that metal. Photographs of devices, type of applied coatings, and microstructures of ceramic oxide coatings are shown in Figure 9. The configuration and relative size and positioning of fixation devices in the mandible area of a rhesus monkey skull are shown in Figure 10. Tantalum fixation devices were formed by first cold rolling tantalum sheets to 25 mils in thickness, cutting strips and electron beam welding the strips at right angle, cutting and shaping specimens to size, bending the specimens in a specially made fixture so as to better fit the contour of the mandible, and then applying coatings according to previously described procedures. The ridge section, designed to extend into a slotted section of the bone and provide support, was made about 0.4 cm wide by about 1.2 cm long. The back plate extended about 0.6 cm beyond the ridge section in both directions to accommodate screw holes sufficiently removed from the ridge section to permit solid anchoring of the specially made No. 2-56, tantalum screws in the bone.



4X

Tantalum Coupon, No. 38R

2E168

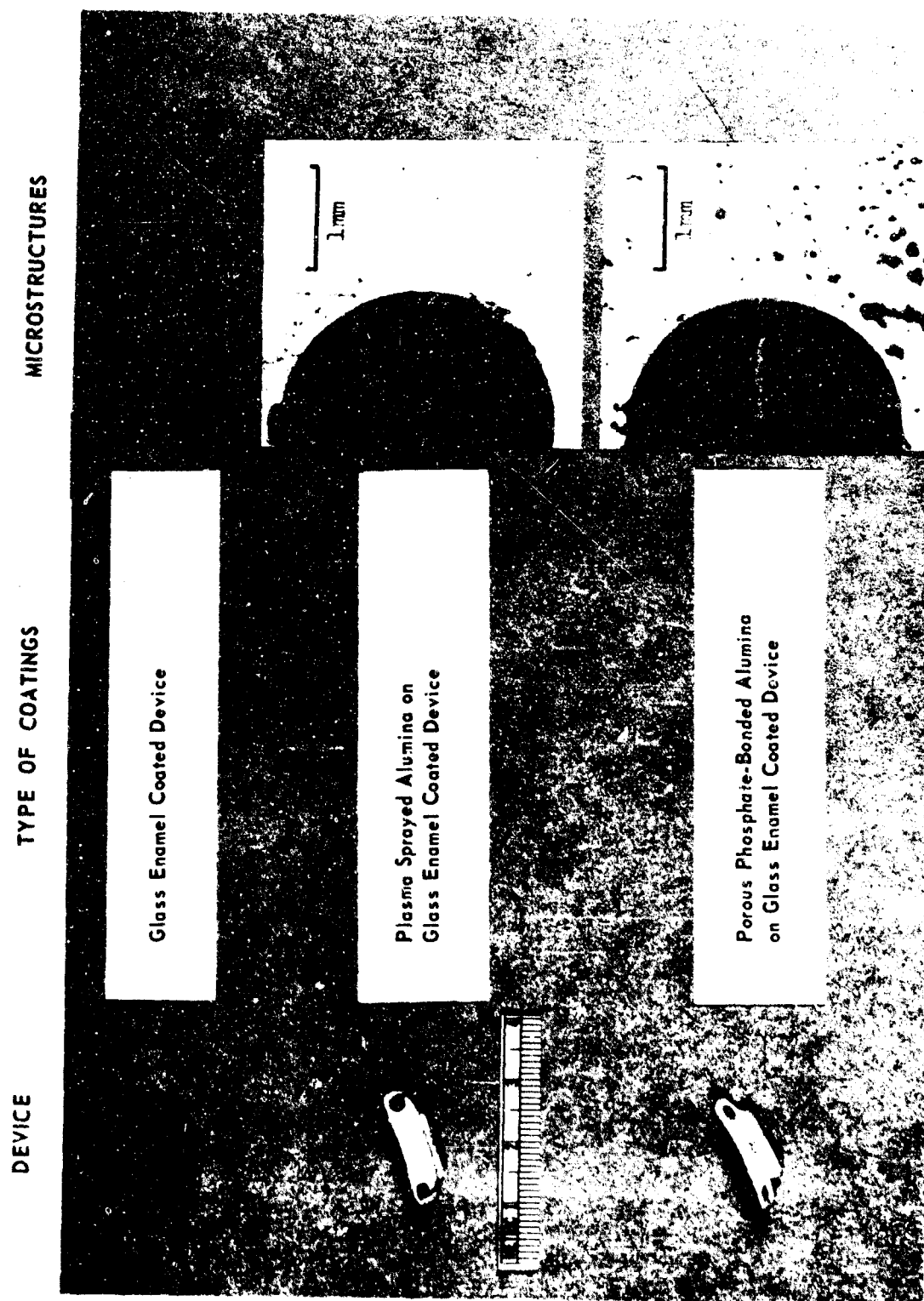


4X

Vitallium Coupon, No. 38C

2E169

FIGURE 8. PLASMA-SPRAYED ALUMINA COATINGS ON
TANTALUM AND VITALLIUM



CERAMIC COATED TANTALUM FIXATION DEVICES

FIGURE 9.



FIGURE 10. PHOTOGRAPHS SHOWING MONKEY SKULL AND RELATIVE SIZE, CONFIGURATION, AND POSITIONING OF CERAMIC-COATED SECOND-GENERATION FIXATION DEVICE

Alumina coatings were easily applied to glass-coated fixation devices by direct plasma spraying. The coatings were adherent and had good coverage on edge surfaces. Porous phosphate-bonded coatings were applied by spraying a thin coating of a slurry mixture of foam Composition 29-10 on each device, rapidly heating the device in an open Fisher burner flame to bloat the coating, and then lightly grinding the coating surface to produce open pores. All devices then were cured at 650 F for 4 hours to assure development of a stable bond. Initial procedures in applying phosphate-bonded coatings by a troweling technique and subsequently grinding the coating to the desired thickness were not satisfactory in applying coatings to fixation devices. Cured coatings troweled on fixation devices were difficult to uniformly grind to a thickness of about 0.6 to 0.8 mm without cutting into the substrate metal.

Figure 11 is a photomicrograph showing a cross section of a second generation fixation device with applied glass and plasma-sprayed alumina coating. As apparent from the photomicrograph, the 0.20 to 0.25-mm-thick oxide coating was uniformly bonded to the underlying glass enamel. The average thickness of the glass coating was about 0.06 mm. Although the glass coating contains numerous air pores, the pores are not interconnecting, and the coating is, therefore, impervious.

Initial or first-generation devices were larger than the second-generation devices that are shown in Figure 9. The ridge section extended the full length of the plate section. The devices were about 2.5 cm long with 1.25-mm-thick ridge and back plate sections. Also, the devices were straight or not shaped to better match the curvature of the mandible and were, therefore, not suited for easy adaption to fracture sections of the mandible. The devices required additional sizing by cutting or grinding off the end of the plate sections. Second-generation devices were, therefore, made shorter, with thinner ridge and plate sections, and shaped for better adaptation to mandible sections.

The flange section of the device was designed to fit into a groove cut in the mandible and thus supply greater stabilization than would be possible through the use of screws alone. Because of the small size of the rhesus monkey mandible, the flange had to be foreshortened in order to allow sufficient room for the screw holes. This compromised the efficacy of the device slightly more than we might have liked. The implant procedure consisted of a through and through resection of the mandible and subsequent fixation.

Fixation of the Through and Through Resected Mandible With Ceramic-Coated Metallic Devices

Rhesus monkeys were the experimental animal. The site to be resected was prepared by the extraction of the deciduous premolars and



25X

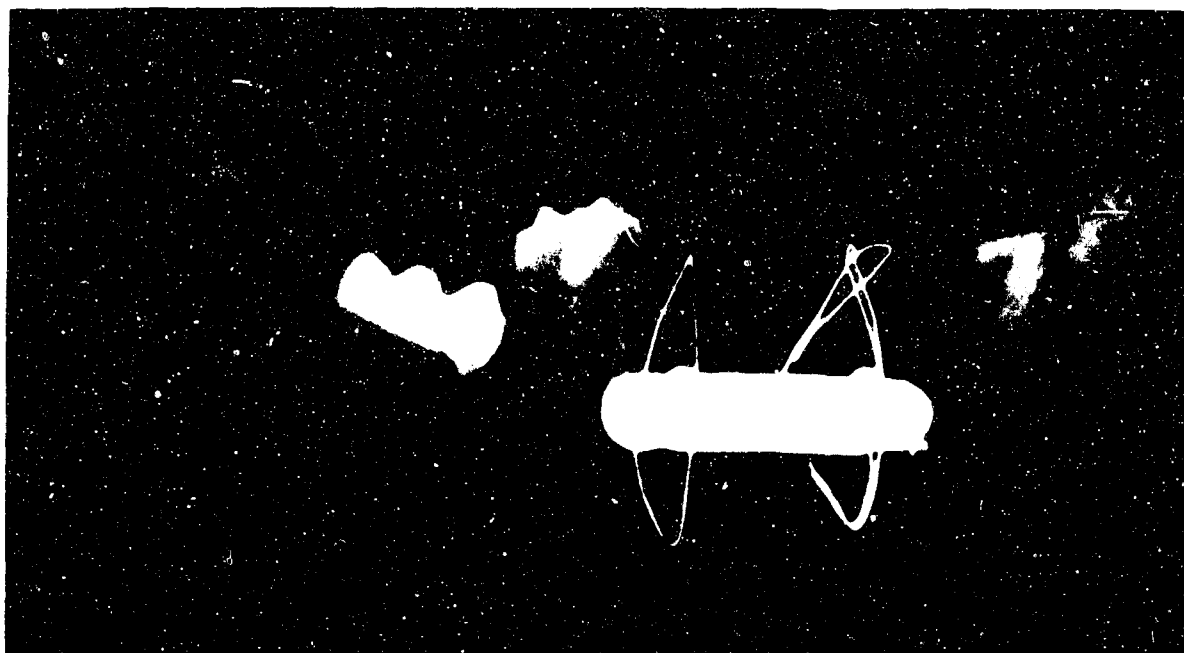
5E649

FIGURE 11. MICROGRAPH SHOWING CROSS SECTION OF SECOND-GENERATION
FIXATION DEVICE WITH THIN IMPERVIOUS GLASS-ENAMEL
COATING AND PLASMA-SPRAYED ALUMINA COATING

permanent first molar teeth and permanent premolar buds. This was accomplished by forcep and exolever extraction utilizing the mucoperiosteal flap with removal of interseptal bone. The defect was allowed to heal for a minimum of eight weeks. The site to be resected was exposed by an incision along the crest of the ridge for the length of the entire quadrant. Exposure of the mental neuro-vascular bundle was made and the foramen crushed and obturated with bone wax. In the mid-portion of the edentulous area a defect was created by cutting through the entire width of the mandible with a diamond disk cooled with a sterile saline spray. The defects ranged from three to eight millimeters. The cut ends were obturated with bone wax for the control of hemorrhage.

The ceramic-coated metallic implant was placed on the surgical site. The buccal flange portion of the implant was traced on the buccal cortical plate. A crosscut fissure burr in a straight handpiece was used to remove enough cortical plate to accommodate the insertion of the buccal flange portion of the fixation device. The groove ended in a buccal-lingual direction, into the cancellous medullary bone, and moderate hemorrhage was controlled with bone wax. With the device in place the screw holes were marked, the device removed, and the holes drilled and tapped. The device was returned to the site and the procedure completed. Tantalum wire was employed by circumferential wiring through the slots of the screws to function as safety wires. Catgut sutures were used to complete closure of the site. One cc of Longicil was given as a postoperative antibiotic.

Figures 12 and 13 show the roentgenographic appearance of the mandible from a monkey who was sacrificed one month after a through and through resection in which a 3-mm segment was removed. The free ends were stabilized by means of a phosphate-bonded ceramic-coated metallic device. Note the radiodense callus on the buccal aspect and on the anterior border of the mandible. Note the width of the defect, the depth of the screws and the buccal flange of the L-shaped device. Note that no areas of resorption around the device can be seen. The implant was firmly held in place. The tissue surrounding the device had a gritty feel when probed with a sharp instrument. The tissue around the screw head was grossly less calcified than the more distant portions of the callus. The reparative tissue had closely approximated the anterior end of the device. Removal of the screw necessitated moderate pressure. The tissue underlying the ceramic had a healthy appearance when compared with other areas of normal healing seen in that portion of the anterior segment where no metal or ceramic had contacted tissue. Micrographs were taken in the area of the anterior segment. The histologic features noted there were as follows: the tissue which abutted against the ceramic surface of the device was composed of highly cellular fibrous tissue which contained marked increases in vascular elements. The latter were seen as dilated and tortuous endothelial-lined channels. Small fragments of nonvital bone were also apparent. This tissue was densely infiltrated with chronic inflammatory cells and was markedly edematous. The area around the screw hole and along the buccal groove of the device showed similar tissue. Adjacent to this highly inflamed fibrous tissue a zone of osteogenic fibrous tissue was seen. This tissue, in turn, abutted on reparative bone that was formed from the endosteal cortical bone and was the major



FIGURES 12 AND 13. ROENTGENOGRAPH OF RESECTED RHESUS MONKEY MANDIBLE SHOWING THROUGH-AND-THROUGH RESECTION OF MANDIBLE STABILIZED WITH A CERAMIC-COATED METALLIC FIXATION DEVICE.

Note new bone proliferating in gap and buccal and lingual callus. Note that no areas of resorption can be seen.

contributor of spanning callus. There was active periosteal callus seen in the anterior segment also. As sections were cut in a buccal-lingual depth, it was determined that new or reparative bone surrounded the device with the exception of the narrow zone of highly vascular connective tissue.

We experienced our only real failure using this technique on one monkey, which was a result of exfoliation of the metallic device. This was due to improper preparation of holes for the screws which resulted in our being unable to retain the screws properly. The device was thus wired in place with the result that within one week the device protruded into the oral cavity and all stabilization was lost. We therefore removed the device, leaving the ends of the mandible floating. The roentgenograph (Figure 14) shows the implant site four months postoperative. There is a continuous union of a fibrous type and extensive bone resorption of the free ends of the mandible has taken place.

Preliminary Evaluation of Nitinol as a Biomaterial

Small cylinders of Nitinol approximately 3 mm in diameter by 12 mm in length were implanted subcutaneously in rats for a period of six months. Cylinders of Nitinol were implanted into six rats--one cylinder in each one. Six blocks of tissue were examined. The specimens consisted of 1.5 by 3-centimeter ovoid pieces of rat skin grossly containing the Nitinol specimen in their mid-portion. After removal of the Nitinol specimen, the implant site represented a cystic space surrounded by a dense, well demarcated fibrous connective tissue membrane. This membrane in most instances was 3 to 10 cell layers thick, with fibers running parallel to the space. The stroma immediately subadjacent to this area exhibited little reaction in the presence of the implant material. Small foci of extravasated blood were noted in some instances, but the only evidence of chronic or acute inflammatory cell infiltrate was minimal lymphocytes subadjacent to the fibrous membrane. Vascularity was not increased in the implant area as compared to control tissue or tissue areas remote from the site. Nerve tissue elements were not increased. We have determined from this experiment that response of rat subcutaneous tissue to Nitinol implants appears to be very similar to the response to other relatively inert metals such as 316 stainless steel and Vitallium. We therefore conclude that further, more sophisticated implant studies should be conducted, including implantation of Nitinol specimens into bone.

CONCLUSIONS AND RECOMMENDATIONS

This study has resulted in the development of two ceramic foam materials--a phosphate-bonded alumina foam and a calcium aluminate-bonded alumina foam. Both, upon being implanted in rhesus monkeys, have appeared



FIGURE 14. MANDIBULAR RESECTION 4 MONTHS AFTER EXFOLIATION OF STABILIZATION DEVICE

The device had become loose within 1 week from time of implantation. Note the extensive resorption and fibrous union.

to indicate a rather high degree of biocompatibility for periods up to five months. We recommend, therefore, that further work to determine both biocompatibility and to optimize physical characteristics be conducted. Phosphate-bonded alumina materials, in particular, owing to our particularly favorable results with this material should be characterized for such physical properties as modulus of elasticity, bend strength, and impact strength characteristics to provide a basis for further assessing the use of such materials for bone prostheses. A ceramic-coated metallic device was developed which successfully stabilized mandibles when segments from 3 mm to 8 mm in length had been removed. Although functions was effectively restored and new bone proliferated in the gap, we believe that additional concepts need to be developed and investigated before accepting or rejecting this concept as a reasonable means of achieving a permanent repair. The use of Nitinol as a biomaterial continues to be an intriguing concept. Initial studies have indicated a probable high degree of biocompatibility. We recommend, therefore, that the implant program be expanded to include the implantation of Nitinol specimens in muscle tissue as well as in bone.

FUTURE WORK

The biocompatibility of phosphate-bonded alumina foam materials demonstrated in this study has indicated the potential use of a new class of materials (chemically bonded ceramics) which may have significant potential as implant materials. However, further research is needed to fully assess the potential uses and application of such materials.

Chemically bonded ceramics are used extensively for high temperature applications; therefore, little attention has been devoted to property measurements of materials cured at low temperatures. Such materials may have significantly different properties from sintered ceramics owing to the presence of hydrate bonds. Desirably, materials selected for implants should have properties similar to those of bone. Phosphate-bonded alumina materials should be characterized for such materials for bone prostheses. The effect of long-term exposure of chemically bonded ceramics in acidic and basic solutions which closely match the conditions of body fluids on the physical properties of such ceramics needs to be investigated.

Phosphoric acid reacts with other oxides, besides alumina, to form adhesive or cementitious materials⁽⁹⁾, many of which may be suitable for bioceramic applications. Zinc and other phosphate cements are used extensively as dental cements. Preliminary effort on phosphate-bonded chrome-alumina indicate interesting properties for these materials. The development of calcium phosphate materials similar or identical in composition to bone may be feasible.

Specially designed tantalum fixation devices containing thin impervious glass coatings with overlaying ceramic oxide coatings were developed. The oxide coatings were applied so as to permit tissue attachment and/or bone ingrowth to firmly anchor the device during the healing period or during restoration of the functional body member. Plasma-sprayed alumina coatings on glass-coated fixation devices were strong, relatively dense, and had rough surfaces. Applied phosphate-bonded alumina coatings were porous and adherent to the underlying glass.

Outside of biomedical applications, little need exists for applying strong, adherent, oxide coatings with specially designed pore structures and impervious underlying coatings on metals. Therefore, the further development of devices with coatings designed to meet these needs will rest on the conception of new methods and techniques of applying such coatings. Application of alumina coatings with specified pore structures might be achieved by plasma spraying mixtures of alumina and either presized silica or carbon particles. The pore structure then would be attained by dissolving out the silica with acid or burning out the carbon particles. Also, porous chemically bonded coatings might be attained by firing devices with applied coatings containing carbon particles.

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13. ABSTRACT Ceramic and ceramic composite materials and devices were developed for specific maxillofacial applications. These applications included: (1) Replacement of hard tissue voids in low stress areas with a phosphate-bonded alumina-foamed ceramic and a calcium aluminate-bonded alumina foam, (2) Development of porous ceramic-coated metallic devices for stabilization of mandibles with avulsed segments. Efforts to date have been rewarding. Using the rhesus monkey for all experimental implant work, incorporation of porous ceramic foam prostheses to eliminate maxillary defects has been accomplished. Also, we have succeeded in stabilizing the mandible where segments of from 3-8 mm were removed. Bridging of the gap with new bone occurred within six weeks resulting in a total regeneration of the resected area with restoration of normal mandibular function.		

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		ROLE	WT	ROLE	WT	ROLE	WT
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